

REMARKS

Claims 1-30 are pending, of which claim 26 is amended to correct a minor informality and new claims 29-30 are added consistent with the election. Support for new claims 29-30 is found in the disclosure of pegylated interferon and ribavirin as possible additional agents for combination therapy, for example, at page 7, lines 21 and 30, pg. 14, lines 20-25, pg. 15, lines, 11-12, pg. 19, lines 19-30, pg. 25, lines 5-16.

This is in response to the Office Action dated January 10, 2005, setting forth a 1 month period for reply. At page 2 of the office action, the examiner sets forth a restriction requirement requiring restriction to one of the following inventions under 35 USC 121:

- I. Claims 1-3, drawn to a pharmaceutical composition and a kit
- II. Claims 4-26, drawn to a method of treating or preventing HCV infection
- III. Claim 27, drawn to a method for validating an assay
- IV. Claim 28, drawn to a method for determining the relative effectiveness of a compound

At page 3, the examiner also indicates that claims 3 and 25 are generic to a plurality of disclosed patentably distinct species comprising an additional agent, and requires an election of a single disclosed species thereof (i.e. a genus and a single disclosed species of said genus with respect to the additional agent).

In response, Applicants herein elect Group II of the restriction requirement, Claims 4-26. In response to the election of species requirement, Applicants herein elect as the first additional agent pegylated interferon (which is an immunomodulatory agent; see pg 7, line 30) and as the optional second additional agent ribavirin (which is an antiviral agent; see page 7, line 21). Thus, with respect to claims 25 and 26, both directed to combination therapy, Applicants herein elect a method wherein the additional agent is pegylated interferon and the optional second additional agent is ribavirin. New claims 29 and 30 are more specifically directed to this election.

Applicants appreciate the Examiner's inventorship notice at page 3 of the office action and will correct inventorship herein as may be necessary.

Applicants appreciate the Examiner's indication at page 4 of the office action that Rejoinder Practice may be applicable in the present application. Applicants herein specifically request rejoinder of the non-elected subject matter of the present application to the extent possible under the USPTO's Rejoinder Practice.

Applicants also appreciate the Examiner's advisory notice with respect to trademarks at page 4 of the Office Action. Applicants will make any necessary corrections regarding trademarks at a later point during prosecution. To expedite this process, the Examiner is requested to more specifically indicate the corrections that are necessary with respect to trademarks.


Applicants also wish to direct the Examiner's attention to two literature references published subsequent to the filing of the present application (copies are enclosed): Lamarre et al., "An NS3 protease inhibitor with antiviral effects in humans infected with hepatitis C virus", *Nature*, vol. 426 (2003), pgs. 186-189; and Hinrichsen et al., "Short-term Antiviral Efficacy of BILN 2061, a Hepatitis C Virus Serine Protease Inhibitor, in Hepatitis C Genotype 1 Patients", *Gastroenterology*, vol. 127, no. 5 (2004), pgs. 1347-1355. These references describe results obtained in clinical studies with BILN 2061 in HCV infected patients, demonstrating significant reductions in viral loads. Applicants submit that such published results are particularly pertinent for the Examiner's consideration in connection with the examination of the present application. These clinical studies and results were briefly mentioned in the present application at page 3, lines 1-11.

In view of the above remarks, Applicants respectfully submit that this application is now in condition for early examination. If any points remain at issue which can best be resolved by

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way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,


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